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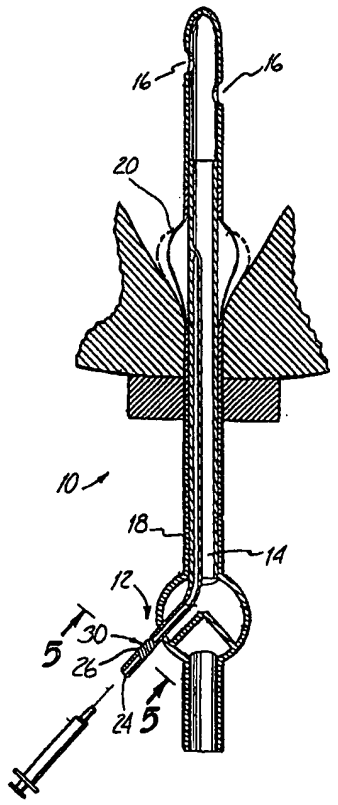
(54) Title: INTRAURETHRAL URINARY CONTROL CATHETER

(57) Abstract

The present invention provides an intraurethral urinary control catheter including a urine flow controlling valve and a self–sealing microvalve for enabling and facilitating the use of a blunt needle or cannula for filling and emptying the balloon. The microvalve enables the needle or cannula to enter the inflation tube of the catheter with minimal resistance, yet adequately seals when the balloon is full and the needle or cannula is removed.



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TITLE: Intraurethral Urinary Control Catheter

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to catheters and, more specifically, to a balloon-type, self-retaining intraurethral urinary catheter including a urine flow controlling valve and an inflation valve.

2. Description of Related Art

Intraurethral urinary catheters for evacuating the bladder are known, including those known as "Foley" catheters which typically include a balloon at one end. After a Foley-type catheter is inserted, the balloon being positioned in the bladder, the balloon is filled with air, water or another suitable inflating solution or substance, thereby preventing the catheter from leaving or being withdrawn from the bladder until the balloon is emptied. This type of catheter also may be referred to as indwelling or self-retaining.

U.S. Patent 5,306,226 (Salama, the inventor of the present invention) discloses a self-retaining catheter including an improved balloon arrangement. A urine tube extends through a generally pear-shaped balloon provided for inflation in the user's bladder. A control valve is located along the urine tube for controlling the flow of urine. An inflation tube extends along the length of the urine tube into the balloon, and has an inlet end for receiving inflation fluid for inflating the balloon. The inlet end is normally closed except when opened by a blunt needle for filling or emptying the balloon. The use of the catheter is described. U.S. Patent 4,968,294 (Salama) also is directed to catheters, disclosing a urinary control valve and method of using it. Both of these above-mentioned Salama patents are incorporated herein by reference.

A number of patents disclose septum valving or sealing structures. U.S. Patent 5,188,607 (Wu) discloses a valve catheter connector assembly including a resilient sleeve which acts as the

hub of the catheter for receiving the male connector tube while sealing the catheter tube against retrograde blood flow until the male connector is fully inserted.

U.S. Patent 5,215,537 (Lynn et al.) discloses a septum for a blunt cannula for coupling intravenous conduits and the like. The Lynn et al. patent addresses the concern of inadvertent needle sticks stemming from the use of sharp needles to connect secondary conduits to vascular catheters. Lynn et al. note that Baxter Health Care Corporation is marketing a connector including a blunt cannula and a septum with a pre-perforated slit.

U.S. Patent 5,106,054 (Mollenauer et al.) and 5,474,536 (Banaldo) disclose other valve apparatus for medical use. The Mollenauer et al. self-sealing valve comprises an elastomeric body having a passage extending therethrough which is held in compression by an elastomeric sleeve disposed around the body. The Banaldo medical valve includes an elastomeric self-sealing valve element which may be pierced by an external needle to insert a catheter. In one embodiment, the Banaldo valve element may be pre-slit and opened by an internal insert.

It would be advantageous if a self-sealing valve could be integrated with an intraurethral urinary control catheter such as those disclosed in the Salama patents, particularly with the inflation tube thereof. Such an improved catheter would be particularly advantageous for facilitating patient use of catheters, reducing the possibility of needle stick injuries in home and clinical settings, and for improving the convenience and comfort of catheter use.

SUMMARY OF THE INVENTION

The present invention provides a balloon-type urinary control catheter including a self-sealing microvalve for enabling and facilitating the use of a blunt needle or cannula for filling and emptying the balloon. The microvalve enables the needle or cannula to enter the inflation tube of the catheter with minimal resistance, yet adequately seals when the balloon is full and the needle or cannula is removed. The valve will accommodate needles or cannulae of various sizes.

The microvalve of the present invention includes a precut slit through which a blunt

needle (e.g., a 23 gauge needle) can pass in order to fill and empty the balloon. Prior to this invention, the inflation tube (of the typical catheter, e.g., a Foley catheter) was large and bulky, and a syringe tip was used for inflating and deflating the balloon. The microvalve is friction fit in the valve housing, i.e., the inflation tube, and requires no adhesive to hold it in place in the tube.

The catheter of the present invention is an intraurethral, balloon-type urinary control catheter including an elongated generally cylindrical catheter body with a urine tube having an inlet opening for receiving urine when the catheter is placed in a user, an outlet outside the user's body from which urine may flow and a control valve located generally between the inlet opening and outlet for controlling the flow of urine. It includes an inflation tube operably coupled to a balloon generally adjacent to one end of the inflation tube and the inlet opening. An inflation valve, the microvalve of the present invention, is adjacent to the other end of the inflation tube, and comprises a generally cylindrical, solid valve body formed substantially of compressible, resilient elastomeric material. The valve body has two flat ends, a needle guide being countersunk in one end and a needle stripper countersunk in the opposite end. The valve has a slit in the generally central portion and an unslit region adjacent to each end. Thus, the valve body is substantially split into two generally hemispheric portions. It is received in a housing portion of the inflation tube which exerts a compressive force on the valve body. The two valve body portions each have a facing surface and the force exerted by the inflation tube housing portion, which is slightly thicker in the wall than the remainder of the inflation tube, and/or has a smaller inner diameter than the remaining portion of the inflation tube, urges the facing surfaces together.

The catheter of the present invention is intended for use in the clinical and hospital settings, as well as for "home" use and use outside the clinical or hospital setting by other than professional health care providers. One advantage of the catheter and microvalve of the present

invention is increased comfort during use and ease of use (including inflation and deflation of the balloon). Another is that a blunt or dull needle or cannula may be used to fill and empty the balloon, thereby reducing the risk of needle sticks and making the catheter easier to use. The catheter of the present invention is much less bulky than the typical catheter, less irritating for the user, and includes a microvalve with a needle guide and centering opening at one end.

Other features and advantages of the present invention will become more fully apparent and understood with reference to the following description and to the appended drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an elevational view of one embodiment of the catheter with the microvalve of the present invention.

Figure 2 is an elevational view of another embodiment of the catheter of the present invention.

Figure 3 is an elevational view, in cross-section, of the microvalve of the present invention.

Figure 4 is a cross-sectional view taken along lines 4-4 of Figure 3.

Figure 5 is a cross-section taken along line 5-5 of Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The Figures depict the catheter 10 of the present invention and features and components thereof, including the microvalve 12 of the present invention.

With regard to means for fastening, mounting, attaching or connecting the components of the present invention to form the catheter as a whole, unless specifically described as otherwise, such means are intended to encompass conventional fastening means and methods suitable for use with synthetic and natural elastomeric materials. Such fastening means and methods include adhesives, friction fitting, chemical and sonic welding, heating, deformation and the like. Unless

specifically otherwise disclosed or taught, materials for making the components of the present invention are selected from appropriate synthetic and natural elastomeric materials such as silicone, latex, silastic and the like, and appropriate forming methods including casting, dipping, extruding, molding and the like may be used.

Any references herein to front and back, right and left, top and bottom, upper and lower and horizontal and vertical are intended for convenience of description, not to limit the present invention or its components to any one positional or spacial orientation. Such terms are to be read and understood with their conventional meanings.

Referring then to the Figures, Figures 1 and 2 depict two embodiments of the catheter 10 of the present invention incorporating an inflation/deflation controlling microvalve 12. The catheters 10 have a generally cylindrical body including a urine tube 14 with at least one inlet 16 adjacent to one end of the catheter to receive urine while the catheter is in place in the bladder. A fill or inflation tube 18 extends generally along or parallel to the urine tube 14. An inflatable balloon 20 (shown in phantom in Figure 2) is generally adjacent to or at one end of the inflation tube 18, generally adjacent to the inlet 16. The inflation tube 18 has an inlet end 24 adapted to receive the delivery end of a filling device such as a syringe or pump device containing liquid or gas for inflating the balloon.

In the catheter 10, the inflation tube 18 includes a microvalve housing region 26 adjacent to the inlet end 24 adapted to receive the microvalve 30, depicted in more detail in Figures 3 and 4. The microvalve housing region 26 has a thicker wall and/or a smaller inner diameter (lumen) than the remainder of the inflation tube 18. The microvalve 30 is designed for use with either of the embodiments of the catheter 10 depicted in Figures 1 and 2. The microvalve 30 includes a body 32 formed of a compressible, resilient elastomeric material. The body 32 is generally solid and cylindrical and has two generally flat ends 34, 36. At one end 34, a cannula or needle guiding recess 38 is provided, and at the other end, a cannula or needle stripping recess 40 is

provided. The valve body 32 includes a generally central region 42 and an elongated central axis indicated at line "A". The central region 42 has slit 44, sliced (i.e., cut or slit) into place during manufacture of the valve 32, whereby the body 32 is substantially, but not completely, split into two generally hemispheric portions 46, 48 each having a generally flat facing surface 50, 52. Adjacent the ends of the slit 44, between the needle receiving and needle stripping or wiping recesses, 38, 40, respectively, and the ends of the slit 44, the body 32 includes thin unslit regions, both indicated 54.

Figures 4 and 5 are cross sectional views of the microvalve 30. Figure 5 depicts the microvalve 30 placed in the inflation tube 18 of the catheter 10 depicted in Figure 1. The inflation tube 18, particularly the housing region 26 thereof, of the catheter 10 acts as a housing and, because the inner diameter of the inflation tube 18 is relatively less than the outer diameter of the microvalve 30 and the tube 18 is made of a resilient elastomeric material, the inflation tube 18 tightly encompasses the microvalve body 32. Thus, unless penetrated by a needle or cannula, the valve 30 is closed, i.e., the facing surfaces 50, 52 are in contact. The inflation tube 18 presses radially inwardly against the microvalve body 32 with sufficient force to prevent the flow of inflation fluid through the slit 44 after the needle is withdrawn, and wipes the needle as it is being withdrawn. This advantage of the present invention is facilitated by providing an inflation tube 18 with an inner diameter of approximately .060 inches and a microvalve body 32 having an outer body diameter of approximately .117 inches.

In use, the catheter 10 is placed in the user's body in accordance with the teachings of the above-referenced and incorporated Salama patents. To fill the balloon 20 after the catheter 10 is in place, a relatively blunt needle is inserted into the inlet opening 24 of the inflation tube 18 and into the needle guiding relieved area 38 of the valve body 32, which directs and helps align the needle with the elongated central axis of the valve body 32. The needle penetrates the first unslit area 54 inside and adjacent to the guide recess 38 and, once the unslit area 54 is pierced, the

needle simply separates the facing surfaces 50, 52 of the microvalve body as it is advanced toward the needle wiping opening 40 at the other end of the microvalve body 32. When it approaches that end, it penetrates the unslit area 54, enters the needle stripping recess, and the inflating air or solution may be injected into the balloon 20.

Once the balloon 20 is filled, the needle or cannula may be removed from the microvalve 30. As the needle is removed, the generally conical surface 58 at the bottom of the cannula stripping area 40 helps removes filling liquid from the exterior surface of the needle, preventing its infiltration between the facing surfaces 50, 52. As the needle is removed further, the opposing faces of the central slit portion of the microvalve body 40 close around the shaft, point and bevel of the needle or cannula to prevent the leakage or flow of inflating fluid or solution out of the balloon 20. The compressive force exerted on the microvalve body 30 by the inflation tube 18 serves to keep the slit 44 tightly closed while the catheter 10 is in use.

For removal of the catheter 10, the balloon 20 is emptied by reinserting a blunt needle into the needle guide 38, through the valve body 32 and into the inflation tube 18, whereupon the balloon filling fluid, air or solution may be aspirated or withdrawn. If urgent removal of the catheter is indicated, or if a cannula or needle suitable for deflating the balloon is not at hand, the inflation tube may be pierced, cut or sliced adjacent to the microvalve between the microvalve and the balloon to empty the balloon. When the balloon is deflated, the catheter may be removed.

It should be appreciated that the microvalve body 30 may be made of any suitable resilient, preferably soft, compressive material such as elastic materials like surgical rubber, silastic or silicone. Silicone is the preferred material, particularly that available from Bayer Silicone under the name Baysilone LSR 4040. A preferred cut or slit 44 in the valve body 32 is depicted in Figures 3 and 4 wherein the centerline of the slit 44 is generally coaxial with the central elongated axis A of the valve body 32 and creates two flat facing surfaces embedded

centrally in the valve body 32, but other shapes of cuts or slits may be used and the ends of the slit may be further extended to or removed from one or the other of the needle guiding or needle stripping relieved areas. Similarly, the side edges of the slit 44 may be moved toward or away from the cylindrical peripheral side wall of the microvalve body 32 as long as the structural integrity and self-sealing capacity of the body 32 is not reduced. The cannulae or needle guiding recess is depicted as stepped inwardly toward the central axis of the body, but it could be smoothly tapered inwardly. The microvalve body 32 and inflation tube 18 can be any selected size, thickness or diameter. While smaller sizes of the catheter are generally preferred, larger sizes of the tube 18, particularly adjacent to the inlet end 24 will facilitate its use by patients or users, particularly older people, but the relative size of the tube and valve, particularly the inner diameter of the tube 18 and the outer diameter of the valve body 32, should be such that the inflation tube 18 provides a sleeve arrangement for the microvalve body 32 and applies sufficient compressive, radial force to the microvalve body 32 both to hold the body 32 in place in the tube 18, preferably without adhesive, and to keep the internal flat facing surfaces 50, 52 of the valve 30 tightly together when a needle is not inserted into the valve. The present invention advantageously allows for the use of a blunt needle or a small, dull plastic cannula.

The appended drawings are provided to illustrate and further describe the present invention. Although a description of a preferred embodiment has been presented, various changes, including those mentioned above, could be made without deviating from the spirit of the present invention. It is desired, therefore, that reference be made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

CLAIMS

What is claimed is:

1. A urinary control catheter including a urine flow controlling valve and a valve for use in filling and emptying a balloon.

2. The urinary control catheter according to claim 1, wherein the valve for use in filling and emptying the balloon comprises a valve body lodged in an inflation tube in fluid communication with the balloon.

3. The urinary control catheter according to claim 2, wherein the valve body includes a passageway extending partially through said valve body through which a blunt needle can pass in order to fill and empty the balloon.

4. The urinary control catheter according to claim 3, wherein the valve body is generally solid and resilient, having two ends, and the passageway extends generally in the direction of the ends.

5. The urinary control catheter according to claim 4, wherein the valve body further comprises a rupturable portion adjacent to each end, each said rupturable portion generally between the end of the body and a respective end of the passageway.

6. An intraurethral, balloon-type urinary control catheter comprising an elongated generally cylindrical catheter body with a urine tube having an inlet opening for receiving urine when the catheter is in use, an outlet from which urine may flow and a control valve located generally between the inlet opening and outlet for controlling the flow of urine, an inflation tube operably coupled to a balloon generally adjacent to one end of the inflation tube and the inlet opening, and an inflation valve adjacent to the other end of the inflation tube, said inflation valve comprising a generally cylindrical, solid valve body formed substantially of compressible, resilient elastomeric material, said body having two ends, a slit in a generally central portion of the valve body and an unslit region adjacent to each end.

7. The urinary control catheter according to claim 6, wherein the slit substantially divides the

valve body into two generally hemispheric portions.

8. The urinary control catheter according to claim 7, wherein the two valve body portions each have a facing surface.

9. The urinary control catheter according to claim 8, wherein the valve body is received in the inflation tube whereby the inflation tube exerts a compressive force on the valve body urging the facing surfaces together.

10. The urinary control catheter according to claim 9, further comprising a cannula guide countersunk at one end of the valve body and a cannula stripper countersunk at the other end.

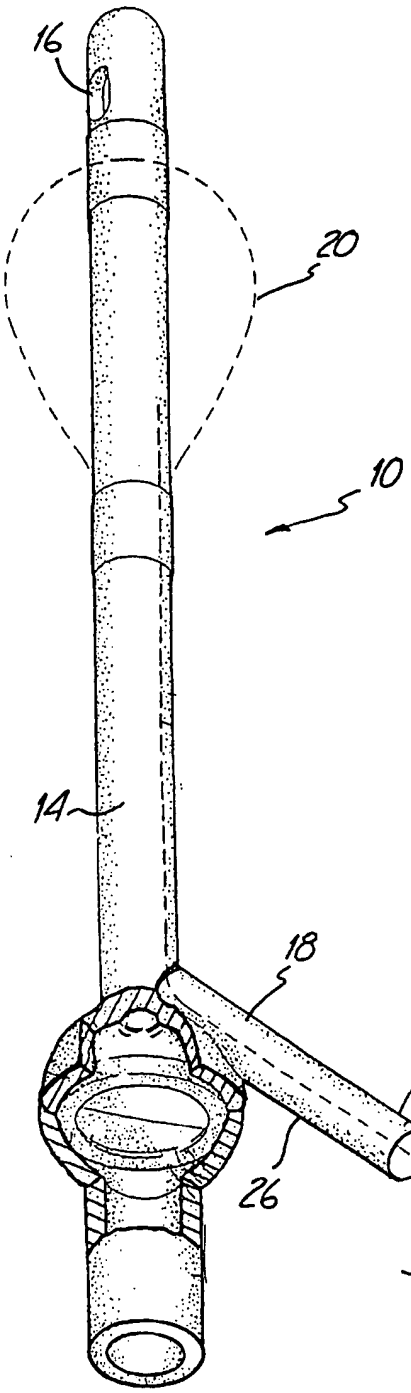

Fig. 2

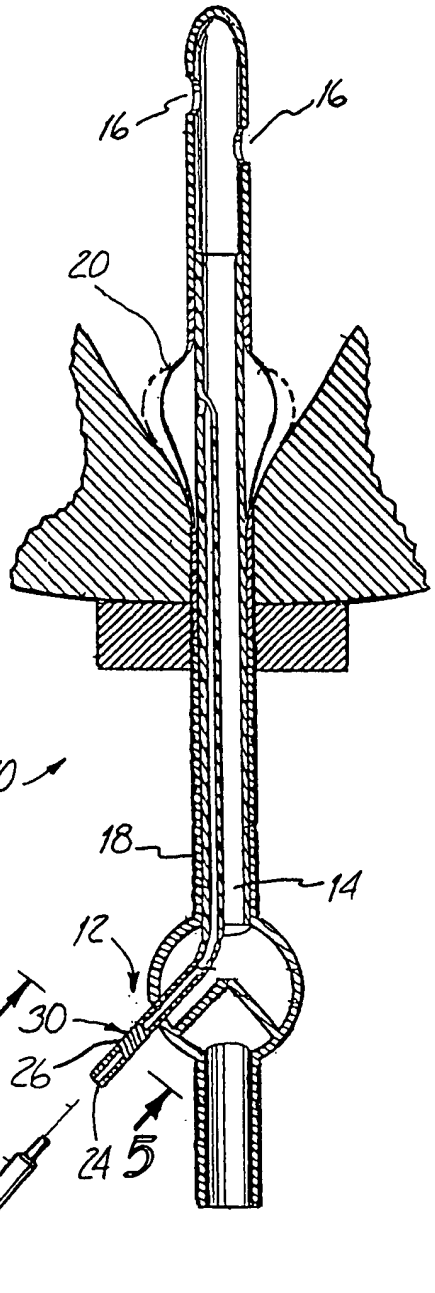

Fig. 1

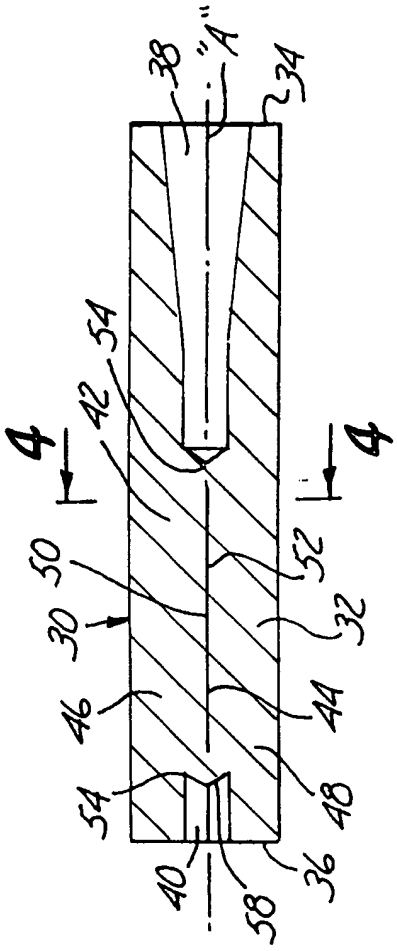

Fig. 3

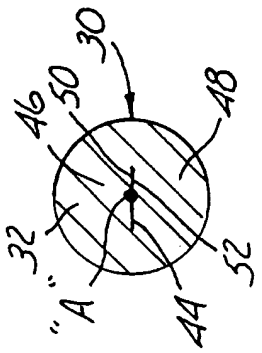

Fig. 4

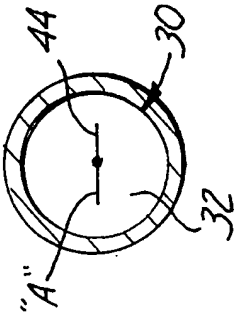

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 25/10
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9626748 A2 (CV DYNAMICS, INC. DBA MEDICAL, INCORPORATED), 6 Sept 1996 (06.09.96), page 11, line 8 - page 12, line 5; page 25, line 26 - page 26, line 7, figures 1,17	1-10
Y	US 5634877 A (F.A. SALAMA), 3 June 1997 (03.06.97), column 1, line 34 - line 63, figure 2	1-10
Y	WO 9308876 A1 (BSD MEDICAL CORPORATION), 13 May 1993 (13.05.93), page 17, line 26 - line 37, figure 3	1-10

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5609583 A (A-HAMID I. HAKKI ET AL.), 11 March 1997 (11.03.97), column 4, line 21 - line 30, claim 1	1-10

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INTERNATIONAL SEARCH REPORT

Information on patent family members

05/10/98

International application No.
PCT/US 98/13519

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9626748 A2	06/09/96	EP 0814863 A	07/01/98
		US 5624395 A	29/04/97
		US 5707357 A	13/01/98
US 5634877 A	03/06/97	US 5693001 A	02/12/97
		US 5800339 A	01/09/98
		US 5306226 A	26/04/94
		AT 151297 T	15/04/97
		AU 654511 B	10/11/94
		AU 8848491 A	20/05/92
		CA 2070430 A,C	23/04/92
		DE 69125594 D,T	04/09/97
		DK 506920 T	20/10/97
		EP 0506920 A,B	07/10/92
		ES 2101756 T	16/07/97
		GR 3023949 T	30/09/97
		JP 2551890 B	06/11/96
		JP 5503239 T	03/06/93
		KR 9706099 B	23/04/97
		RU 2097071 C	27/11/97
		WO 9206731 A	30/04/92
		US 4968294 A	06/11/90
WO 9308876 A1	13/05/93	NONE	
US 5609583 A	11/03/97	WO 9710873 A	27/03/97